

Application No.: 10/772124  
Docket No.: CL2175USNA

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### REMARKS

Claims 1, 2 and 5-22 are pending in the application.

Claims 1, 2 and 5-22 stand rejected under 35 USC § 102.

It is respectfully submitted that entry of the present response and amendment is proper under 37 C.F.R. 1.116 as it:

- (i) places the application in condition for allowance;
- (ii) does not raise any new issues requiring further search of consideration; and
- (iii) places the application in better form for appeal (if necessary).

No new matter has been added

### *Information Disclosure Statement*

Applicants acknowledge that the IDS filed 8/11/05 has not been considered as the references were already cited in the previous action by the Examiner.

### *Claim Rejections – 35 USC § 102*

Claims 1, 2 and 5-22 remain rejected under 35 USC § 102 as anticipated by Philippe et al (US 6280747), hereinafter "Philippe et al" for reasons of record. The examiner maintains that Philippe et al teach the claimed cosmetic ingredients in combination with the claimed protein as illustrated in figures 6A and 7A and that, although Philippe et al do not expressly state that their proteins are water soluble, that water solubility is inherent as they contain the same monomers having the same number of repeats. Applicants traverse.

An essential limitation of Claim 7 is the water solubility of the silk protein (claim 1(a)). Applicants maintain that Philippe et al do not teach water solubility of their protein and that it is not inherently water soluble.

The solubility of recombinant silk proteins in aqueous solution depends on the type of silk protein, the expression system used, and on the chemical and physical environments the protein is exposed to. Recombinant spider silk proteins are expressed in soluble form in bacterial hosts and in both soluble and insoluble forms in yeasts. However, the recombinant spider silk proteins that are expressed in soluble form in microbial systems become insoluble upon purification and are extremely difficult to resolubilize after drying or precipitation (see Arcidiacono et al. *Macromolecules* 35 (2002) page 1262, second col, lines 4-10, and page 1263, second col, lines 27-29; Winkler et al. *Int J. Biol. Macromol.* 24 (1999), page 265, first col, lines 7-14 and page 268, first col, lines 3-7; and Fahnstock Rev. Mol. Biotechnol. 74 (2000), page 115, second col, line 3 from bottom to page 116, first col, line 32. Therefore, the recombinant spider silk proteins described by Philippe et al. that are expressed in microbial systems are insoluble after purification, which limits their effectiveness in personal care compositions.

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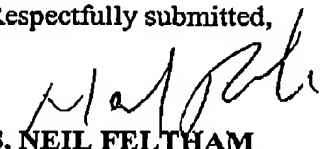
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This sensitivity of silk protein solubility to the conditions the protein experiences is an intrinsic property of the protein that is of functional significance in nature. In the lumen of the spider's silk gland, the natural protein is held in a water-soluble storage form. Exposure to subtle changes in chemical and physical environment (without covalent modification of the protein) as the protein is processed through the spider's system converts the same protein into an irreversibly insoluble fibrous form. Indeed, it is this capacity of silk protein for conversion from soluble to insoluble form under subtle environmental influence and without covalent alteration, that provides the basis for its utility in the instant invention.

As noted by the Examiner, Philippe et al. do not teach how to produce water-soluble silk proteins from those expressed in microbial hosts. Applicants describe several ways to prepare water-soluble silk proteins from microbial hosts. Specifically, the silk proteins may be chemically modified to increase their water-solubility by reacting them with a polar, low molecular weight reactant, as described by Stedronsky in U.S. Patent No. 5,760,004. However this is not the preferred method of solubilizing the spider silk proteins because the chemical modification is likely to supersede or override the protein's natural ability to convert from soluble to insoluble form under subtle physical influences. Preferably, the microbially expressed silk proteins are purified by the precipitation method described by Fahnstock et al. U.S. Patent Application No. 10/704,337, which renders them more water-soluble without interfering with their capacity for subsequent conversion to insoluble form by physical means.

Because Philippe et al. do not teach the use of water-soluble silk proteins from microbial hosts, the references does not anticipate the claimed invention. In view of the foregoing Applicants respectfully request reconsideration of the claims and withdrawal of all rejections.

Respectfully submitted,



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